

## REMARKS

Applicant acknowledges and appreciates the Examiner's reconsideration and withdrawal of the Restriction Requirement imposed in the office action of February 3, 2005.

Upon entry of the present amendment, claims 1-42 will be pending in the instant application. Claims 1 and 22 are amended to more particularly point out and distinctly claim Applicant's invention. Claim 4 is amended to conform to the amendments to claim 1. Claims 22 - 24 and 33 - 40 are amended to correct typographical errors and to correct inaccurate claim dependencies.

More specifically, claim 1 is amended to recite that the nodule extending inwardly from the interior surface of the wrap "is a substantially rigid member having a curved contact surface." Support for the amendment to claim 1 is found in the specification as filed, *inter alia*, at page 4, lines 14-34 and in Figures 3 and 9.

Claim 22 is amended to recite that the wrap has "an interior surface for contacting the body portion," that the pad section loaded with medicament is "attached to the interior surface of the wrap. Support for this amendment to claim 22 is found in the specification as filed, *inter alia*, at page 1, line 31 through page 2, line 6. Claim 22 is further amended to recite that the substantially rigid nodule, which is adapted to contract at least one pre-located acupressure point near the area of the pain "has a curved contact surface" and extends inwardly "from the interior surface of the wrap." Support for the amendments to claim 22 is found in the specification as filed, *inter alia*, at page 1, line 31 through page 2, line 6, at page 4, lines 14-34, and in Figures 3 and 9. Claim 22 is further amended to correct an obvious typographical error ("contract" is replaced with "contact").

Claims 23 and 24, both of which depend on claim 22, are amended to replace "device" with "wrap," since there is antecedent basis in claim 22 for the latter term but not the former.

Claims 33 - 40 are also amended to correct an apparent typographical error that appears in each of these claims. Claims 33 - 40 all refer to “the excipient” of the method of claim 22, which, in fact, does not recite “an excipient.” Accordingly, claims 33 through 40 are amended to recite the “method of claim 32,” which does recite “an excipient.”

Accordingly, the present amendments are fully supported by the specification as filed and no new matter is added.

**THE REJECTION UNDER 35 U.S.C. § 102(e) SHOULD BE WITHDRAWN**

Claims 1-42 are rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Davis *et al.* (U.S. Patent No. 6,074,413 “Davis”). More specifically, at page 2 of the Office Action mailed June 15, 2005 (the “Office Action”), it is alleged that:

Davis *et al.* disclose a wrap having plurality of nodules (74) extending inward from the interior surface of the layer (60), and the wraps incorporate a component such as a separate substrate layer or incorporated into at least one of the continuous layers medicament as claimed (col. 18, line 65 to col. 19, line 16).

It is further alleged at page 2 of the Office Action that “[t]he steps of the method as claimed are inherently carried out as the wrap of Davis *et al.* being used.”

Applicant respectfully traverses and submits that claims 1-42, as amended, are not anticipated by Davis.

Anticipation under 35 U.S.C. § 102 requires that every element and limitation of a claimed invention must be found within a single prior art reference; moreover, each of the elements disclosed in that reference must be arranged as they are in the claim (*see e.g. Karsten Mfg. Corp. v. Cleveland Golf Co.* 242 F.3d 1376, 1383, 58 USPQ2d 1286, 1291 (Fed. Cir. 2001); *Brown v. 3M* 242 F.3d 1349, 1351 (Fed. Cir. 2001); *Perkin-Elmer Corporation v Computervision Corporation* 732 F.2d 888, 894 (Fed. Cir. 1984). Moreover, the disclosure of the cited reference must provide enough detail and sufficient clarity that one of ordinary skill in the art would have recognized the claimed subject matter existed (*see e.g. ATD Corp. v. Lydall, Inc.* 159 F.3d 534, 545 (Fed. Cir.

1998)); that is “[t]here must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention (*Scripps Clinic & Research Fdn. v. Genentech, Inc.* 927 F.2d 1565, 1576 (Fed. Cir. 1991)).

Applicant further notes that an allegation of inherent anticipation must be based upon objective fact and scientific reasoning that demonstrate that the “allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art” (emphasis in the original; citations omitted). (*Ex parte Levy* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Interf., 1990)). In addition the cited reference must disclose each and every limitation of the claimed invention and the location and the location of each element of that disclosure must be identified as well (*Id.* at 1462). Moreover, inherency cannot be based on probabilities or possibilities; the “mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.” (*Continental Can Co. USA v. Monsanto Co.* 948 F.2d 1264, 1269 (Fed. Cir. 1991)).

Applicant respectfully submits that the Examiner has not provided an objective basis for the allegation that Davis discloses nodules extending inwardly from the inner surface of a wrap. As noted above, at page 2 of the Office Action, the Examiner has alleged that Davis discloses nodules (74) extending inwardly from the interior surface (60) of the wrap of Davis. However, element (74) of the DISPOSABLE ELASTIC THERMAL BACK WRAP of Davis is an exothermic composition that is used to fill the heat cells (22) that are disposed within the thermal pack (50) that is incorporated into the disclosed thermal back wrap (*see e.g.* col. 11, lines 13-30 of Davis). Moreover, element (60) is defined as a fibrous layer disposed at the outer surface (30) of the thermal back wrap of Davis (*see e.g.* col. 8, lines 56-57 of Davis). Furthermore, it is apparent that element (74) is disposed between the inner and outer surfaces of the disclosed thermal back wrap (*see e.g.* Fig. 2 of Davis); *i.e.* element (74) does not project inwardly from the interior (body-facing) surface (28) of the disclosed thermal back wrap (*see e.g.* Fig. 2 and col. 7, lines 9-13 of Davis).

In view of the above, applicant respectfully submits that it would be apparent to a skilled worker in this field that an exothermic composition that is confined to the interior a thermal back wrap is not a nodule that extends inwardly from the interior surface of the wrap and that is adapted to contact and exert pressure at a specific location on a body portion. Accordingly, the Examiner has not provided a basis for the allegation that Davis discloses “a wrap having plurality of nodules (74) extending inward from the interior surface of the layer (60).” Therefore, based upon the information cited by the Examiner, Davis does not disclose at least one element recited in independent claim 1 and independent claim 22. Accordingly, Davis does not anticipate the presently-claimed invention. Accordingly, Applicant respectfully requests that the rejection of claims 1-42 as anticipated under 35 U.S.C. § 102(e), over Davis, be withdrawn.

Notwithstanding the above, it appears that the Examiner may have intended to refer to the heat cells (22) that are depicted (but not explicitly numbered) in Figure 2 of Davis, as “nodules.” However, as demonstrated below, the heat cells (22) of Davis are not nodules. That is, for the reasons provided below, it would be apparent to one of ordinary skill in this field, the nodules recited in pending independent claims 1 and 22 are not only structurally and functionally distinct from the heat cells (22) of Davis, they are arranged differently as well.

Therefore, in order to expedite prosecution of the above-identified application, Applicant further submits that, for the additional reasons provided below, Davis cannot be construed as an anticipatory reference. Again, for this analysis, it has been presumed that the Examiner intended to refer to the heat cells (22) of Davis (*i.e.* heat cells are formed by disposing “exothermic material” (74) within a cell formed from continuous layers (70) and (72), as depicted in Figure 2 of Davis) as “nodules.” If this presumption is not correct, Applicant respectfully requests clarification by the Examiner.

Davis discloses a back wrap comprising a thermal pack (50) (Fig. 1, col. 4, lines 15-20, and col. 11, lines 7-12). The thermal pack, in turn comprises heat cells (22) (Fig. 1 and col. 4, lines 15-20), which are empty structures (col. 5, lines 36-42; col. 6, lines 10-19; and at col. 18, lines 25-28) into which an “exothermic composition” (74) is

placed. The heat cells containing the “exothermic composition” are, collectively, sealed with a continuous layer of material (72) at the top and with a continuous layer of material (70) at the bottom of each cell (Fig. 2; col. 11, lines 31-34, and col. 17, lines 50-60). The thermal pack so constructed is further embedded, on both the upper and lower sides, within additional layers of material to generate a multi-layered “laminate” type of structure (*see e.g.* Fig. 2, and col. 17, lines 50-60, ).

Materials chosen for assembly of the thermal back wrap of Davis are those that are initially rigid (*see e.g.* col. 4, lines 1-8) but soften upon heating so as to conform to the contours of the body surface to which the wrap is applied (col. 11, lines 27-35; col. 11, line 64 through col. 12, line 3; col. 5, lines 18-27; and col. 5, lines 46-49). The heat is generated upon exposure of the “thermal composition” to oxygen (*see e.g.* col. 4, lines 15-20).

Accordingly, Davis repeatedly asserts that the disclosed thermal back wraps have “excellent conformity to the user’s back” (col. 2, lines 61-64; *also see* col. 5, lines 25-27 and lines 45-48).

Thus the thermal pack of Davis, and the heat cells thereof, are, in fact, embedded within the thermal back wrap and physically insulated from any direct contact with a body portion. Therefore, even if, solely for the sake of argument, the heat cells (22) of Davis were to be deemed to be nodules (which they emphatically are not), they do not extend inwardly from the interior surface of the wrap, nor are they adapted to contact a specific location on the body, as required by pending independent claims 1 and 22.

As demonstrated above, the thermal back wrap of Davis is intended to conform to the contours of the surface onto which it is applied. Therefore, it would be apparent to one of ordinary skill in this field that tightening the elastic components of Davis’ thermal back wrap would increase the pressure applied by the wrap uniformly over the entire surface of the body part (*i.e.* the back) to which it was applied. Accordingly, even if, solely for the sake of argument, the heat cells (22) of Davis were to be deemed to be nodules (which they emphatically are not) they are not adapted to exert pressure at

a desired specific location on the body portion, as required by pending independent claims 1 and 22.

Moreover, in view of the description of the heat cells (22) and even if, solely for the sake of argument, the heat cells (22) of Davis were to be deemed to be nodules (which they emphatically are not), it would be apparent to one of ordinary skill in this field that the heat cells of Davis provided were not substantially rigid members having a curved contact surface, as required by pending independent claims 1 and 22.

In summary, the heat cells (22) of Davis and the nodules recited in pending independent claims 1 and 22 do not have the same structure, do not provide the same function, and are not attached in the same way to a wrap. Therefore, in view of the above, Applicant respectfully submits that Davis does not disclose the presently-recited nodule that extends inwardly from the interior surface of the wrap, and that is adapted to contact and exert pressure at a specific location on a body part. Consequently, since Davis does not disclose an element recited in each of pending independent claims 1 and 22, Davis cannot anticipate the presently-claimed invention. Accordingly Applicant respectfully requests that the rejection of claims 1-42 as anticipated under 35 U.S.C. § 102(e), over Davis, be withdrawn.

As noted above, the Examiner has also alleged at page 2 of the Office Action that use of the thermal back wrap of Davis inherently carries out the presently-claimed method [which is recited in claim 22]. Again Applicant respectfully traverses this rejection. Applicant respectfully submits that, for the reasons provided herein, the presently-claimed method (claim 22) is not inherently anticipated by Davis.

For all the reasons provided above, Applicant respectfully submits that the thermal back wrap of Davis is both structurally and functionally distinct from the presently-claimed device. More specifically, *inter alia*, Davis does not disclose the presently-recited nodule, which is a substantially-rigid member having a curved contact surface, that extends inwardly from the interior surface of the wrap, and that is adapted to contact and exert pressure at a specific location on a body part.

As noted above, even assuming that the Examiner intended to allege that the heat cells (22) of Davis were nodules, it is apparent that this is emphatically not the case. As demonstrated above, the heat cells (22) of Davis are hollow structures filled with an “exothermic material” that are embedded within the interior of a heat pack which, in turn, is further disposed within the interior of the thermal back wrap. Clearly the heat cells (22) of Davis’ thermal back wrap are not intended to contact the body part to which the wrap is applied. Furthermore, in view of the fact that the thermal back wraps of Davis conform to the contours of the body part to which they are applied, the heat cells (22) of Davis cannot be construed as exerting pressure on a desired acupressure point, as recited in pending method claim 22.

Therefore, for the reasons provided above, Davis does not disclose any element that is or even could be construed as the structural or functional equivalent of the presently-recited, inwardly-extending nodule. Consequently, it follows that use of the thermal back wrap of Davis cannot be construed as inherently, *i.e. necessarily*, performing the steps of the presently claimed method of independent claim 22. Accordingly, Applicant respectfully request that the rejection of claim 22 (as well as that of all the claims dependent thereon) as inherently anticipated under 35 U.S.C. § 102(e), over Davis, be withdrawn.

In summary, Applicant respectfully submits that, for all the reasons provided above, the rejection of pending claims 1-42 as anticipated under 35 U.S.C. § 102(e), over Davis has been overcome. Accordingly, Applicant respectfully requests that the rejection of claims 1-42 as inherently anticipated under 35 U.S.C. § 102(e), over Davis, be withdrawn.

### CONCLUSION

Applicants respectfully requests that the present amendments and remarks be entered and made of record in the instant application. An early allowance of the application is earnestly requested. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same.

No fee, other than that for the extension of time, is believed to be due for this amendment and response. However, should a fee be due, please charge the required amount to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

Date: December 15, 2005

Samuel B. Abrams 30,605  
Samuel B. Abrams (Reg. No.)

By: Michael J. Ryan 41,283  
Michael J. Ryan (Reg. No.)

**JONES DAY**  
222 East 41st Street  
New York, New York 10017  
(212) 326-3939